

REMARKS

I. Claim Objections

The Examiner objected to Claim 20 on the grounds that the word "leur" should be spelled "luer." Applicant has so amended Claim 20. Examiner's objection should therefore be obviated.

II. Claim Rejections Based on 35 U.S.C. §102(e)

The Examiner has rejected Claims 11, 14-25 under 35 U.S.C. §102(e) as being anticipated by Wild (U.S. 6,605,036).

With respect to independent Claim 11, Applicant respectfully disagrees that Claim 11 is anticipated by Wild because Wild fails to teach each and every element claimed by the Applicant. Wild fails to disclose an "irrigation channel comprising a plurality of tubes each having one end coupled in fluid communication to the distal portion of the irrigation channel, each opposite end of the plurality of tubes coupled to the drainage channel so that the plurality of tubes support the irrigation channel inside the drainage channel while at the same time the plurality of tubes being dimensioned to deliver an irrigant from the irrigation channel to a subdural space." (emphasis added). See Claim 11. Because Claim 11 specifies that specific structure of the irrigation channel as having tubes that support the irrigation channel inside the drainage channel these elements must be found

in the Wild reference in order for Wild to be considered a proper reference under 35 U.S.C. §102. There are no such references to such a structure anywhere in the Wild reference. In addition, the irrigation channel of the Wild reference is disposed only at the very end of the distal portion, not along the length of the distal portion as disclosed by Applicant (See for comparison Figure 4-5 of Applicant's application as compared to Figures 16-17 of Wild). Because Wild fails to teach each and every aspect claimed by the Applicant, this rejection should be obviated. Applicant respectfully requests that the previous indication of allowability with respect to Claim 11 stated in the July 11, 2006 Office Action be restored.

With respect to Claim 14, upon which Claims 15, 18-22 and 26-27 depend, Applicant respectfully disagrees that Claim 14 is anticipated by Wild because Wild fails to teach each and every element claimed by the Applicant. The method described in Claim 14 requires the insertion of a dual lumen catheter into a subdural space, followed by draining the subdural space of a subdural fluid collection with the dual lumen catheter. Wild fails to disclose a method for draining a subdural space of a subdural fluid collection. The use of fluid described in the Wild patent is not for purposes of irrigating and draining a subdural space, but rather to continuously clear debris from the optical lens of the endoscopic telescope lens. See Declaration under 37 CFR §1.132

of Dan Lieberman, M.D., submitted herewith and incorporated herein by reference. In treating subdural hematomas the first step must be to drain the subdural space. There is no discussion of using the Wild device for the treatment of subdural hematomas (the only reference to the treatment of subdural hematomas included in the Wild reference and cited by the Examiner relates to a discussion of prior art neurosurgery devices that stand in contrast to the endoscopic Wild device). In addition, any discussion of drainage in the Wild reference relates to separate channels that do not comprise a dual-lumen catheter. Indeed, neither the words "dual" or "lumen" appear anywhere in the Wild reference (and the only reference to "catheter" is in a discussion of prior art references). Because Wild fails to teach each and every aspect claimed by the Applicant, this rejection should be obviated.

With respect to Claim 16, upon which Claim 17 depends, Applicant respectfully disagrees that Claim 16 is anticipated by Wild because Wild fails to teach each and every element claimed by the Applicant. For the same reasons described above that Claim 14 is not anticipated by Wild so too Claims 16-17 are not anticipated by Wild. Wild teaches a surgical instrument for use in endoscopic surgery, not the non-visual treatment of subdural hematomas. This difference is critical, since an endoscopic is a substantially rigid device that only allows 1-2 millimeters of

insertion beneath the bone flap, whereas the flexibility of a catheter, such as the dual-lumen catheter described in applicant's invention, is capable of being inserted approximately 5-10 centimeters under the bone flap. See Declaration under 37 CFR §1.132 of Dan Lieberman, M.D.. Applicant is a board certified neurosurgeon who has been in practice since 2000. *Id.* His practice includes the management of hundreds of patients with subdural hematomas. *Id.* Based on all of Applicant's expertise and experience in the field of neurosurgery generally and subdural hematomas specifically, the use of the endoscope disclosed Wild would prevent proper entry into the subdural space for purposes of subdural evacuation of subdural fluid. *Id.* Applicant respectfully requests that the previous indication of allowability with respect to Claims 16-17 stated in the July 11, 2006 Office Action be restored.

With respect to Claim 23, Applicant respectfully disagrees that Claim 23 is anticipated by Wild because Wild fails to teach each and every element claimed by the Applicant. In addition to the reasons cited above, Claim 23 provides for a tuohy needle, which is then inserted into the subdural space of the skull. There is not a single reference to a tuohy needle in the Wile reference. In the Office Action, the Examiner mistakenly refers to the "outer tube 25" as a tuohy needle, however this is not the case. Wild specifically states that "the outer tube 25 (e.g., of

plastic) constituting an outer sheath part of the shaft 21 of the instrument." See Column 14, Lines 5-7 of Wild. In addition to the aforementioned reasons, and because Wild fails to disclose the tuohy needle element, this rejection should be obviated. Applicant respectfully requests that the previous indication of allowability with respect to Claim 23 stated in the July 11, 2006 Office Action be restored.

With respect to Claim 24, Applicant respectfully disagrees that Claim 24 is anticipated by Wild because Wild fails to teach each and every element claimed by the Applicant. In addition to the reasons cited above, Claim 24 provides for not only a tuohy needle, but a guide wire, neither of which is disclosed in the Wild reference. In the Office Action, the Examiner mistakenly refers to the "steerable push-pull wires" as a guide wire, however this is not the case. Wild specifically states that the push-pull wire is for connecting the handle to the deflector. See Column 2, Lines 41-42 of Wild. The guide wire of Applicant's invention is for guiding advancing a dual lumen catheter to a specific place inside the subdural space (see Claim 24). In addition to the aforementioned reasons, and because Wild fails to disclose either the tuohy needle element or the guide wire element, this rejection should be obviated. Applicant respectfully requests that the previous indication of allowability with respect to Claim 24 stated in the July 11, 2006 Office Action be restored.

With respect to Claim 25, upon which Claims 26-27 depend, Applicant respectfully disagrees that Claim 25 is anticipated by Wild because Wild fails to teach each and every element claimed by the Applicant. In addition to the reasons cited above, Claim 25 provides for a stylette, which is not disclosed in the Wild reference (the word "stylette" in fact fails to appear anywhere in the Wild patent). In the Office Action, the Examiner mistakenly states that the "rigid telescope 2 functions in the same manner as a stylette, to provide temporary rigidity to the catheter," however this is not the case. Wild specifically states that the rigid telescope "functions to provide an optimal view within the surgical field of the distal ends of the instruments along their entire working trajectories." See Column 11, Lines 49-51. The rigid telescope does not provide for "temporary rigidity" nor is it designed to aid a catheter's insertion into a subdural space. These elements of method Claim 25 are simply not disclosed in the Wild reference, making it an improper reference under 35 U.S.C. §102. Applicant respectfully requests that the previous indication of allowability with respect to Claim 25 stated in the July 11, 2006 Office Action be restored.

Therefore, Applicant believes that Claims 11 and 14-25, are not anticipated by the Wild reference.

IV. Claim Rejections Based on 35 U.S.C. §103

The Examiner has rejected Claims 26 and 27 under 35 U.S.C. §103(a) as being unpatentable over Wild as applied to Claim 14 and further in view of DARDIK et al.

The Examiner states that while Wild is silent on the duration of irrigation and drainage of the subdural hematoma, "DARDIK et al. teaches that drains are removed from patients after three days (Abstract)." However, the patients referred to in the DARDIK et al. reference were being treated for thoracoabdominal aortic aneurysm repair (TAAA), not subdural hematomas, which according to the article, were developed as a complication to the original purpose of the surgery. In other words, drainage was not used to treat subdural hematomas, which was a complication that occurred in only 3.5% of the patients, but rather as part of the course of treatment for TAAA. None of the cited references of Wild or DARDIK et al. make the suggestion to insert a dual-lumen catheter into a subdural space for the purpose of evacuation the subdural space of a collection of fluid that has resulted in a subdural hematoma.

In order for the combination of references cited by the Examiner, singly or in combination, to satisfy the obviousness requirement, the prior art references must suggest the desirability of the combination. The mere fact that the references may be combined or modified does not in itself render the resultant combination obvious. In re Mills, 916 F.2d 680

(Fed. Cir. 1990). Furthermore, the level of skill in the art cannot be relied upon to provide the suggestion to combine references. Al-Site Corp. v. VSI Int'l Inc., 174 F.3d 1308 (Fed. Cir. 1999).

It is therefore not sufficient that the endoscope of the Wild reference could be minimally inserted into a subdural space or that a drain could be used as primary treatment for draining subdural hematomas, there must also be a suggestion in these references to the desirability of the use of draining a subdural space of a subdural hematoma and irrigating that space. Furthermore, endoscopic surgery can only be used in conjunction with fluid, and cannot be used in anatomical structures in which little or no fluid is present. The use of fluid described in the Wild patent is not for purposes of irrigating and draining a subdural space, but rather to continuously clear debris from the optical lens of the telescope. In treating subdural hematomas the first step must be to drain the subdural space. See Declaration under 37 CFR §1.132 of Dan Lieberman, M.D., submitted herewith and incorporated herein by reference.

Because none of the cited references of Wild or Dardik et al. make the suggestion to insert a dual-lumen catheter into a subdural space, these rejections should now be obviated. Applicant respectfully requests that the previous indication of allowability with respect to

VI. Conclusion

Applicant respectfully submits that this Amendment Letter, in view of the Remarks offered herein, is fully responsive to all aspects of the objections and rejections tendered by the examiner in the Office Action. None of the cited prior art, nor any combination thereof, discloses a method for treating subdural hematomas that includes the inserting of a dual lumen catheter into a subdural space to remove a subdural collection of fluid. For all the foregoing reasons, the Applicant respectfully asserts that all claims are patentable over the cited prior art and respectfully requests that these Claims be allowed.

The fee for a one-month extension of time is included herewith. It is not believed that this Amendment Letter requires any additional fees, but if there are any fees incurred by this communication, please deduct them from our Deposit Account NO. 23-0830.

Respectfully submitted,

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